

REMARKS

Claims 21, 23 to 25, 27 and 29 to 31 are currently pending in the subject application. Applicants have hereinabove amended claims 21, 23, 25, 27, 30 and 31 to recite that the antibody is coupled to a cytotoxic agent. Support for this amendment to the claims can be found in the specification as originally filed at, inter alia, at page 62, lines 16-18. Accordingly, applicants respectfully request that this Amendment be entered.

Priority

In the February 22, 2008 Office Action, the Examiner asserted that claims 21, 23-25 and 27-31 are not adequately supported by U.S.S.N. 08/894,583 or PCT/US96/02424, of which benefit is claimed. The Examiner asserted that claims 21, 23-25 and 27-31 would be treated as having an effective filing date of January 2, 2004. The Examiner asserted that there is inadequate support for the claimed method "of eliminating cancerous prostate epithelial cells comprising providing an antibody bound to a cytotoxic agent which antibody binds to an outer membrane domain" of PSMA, (emphasis in original).

In response, applicant respectfully traverses the Examiner's rejection. As described in the previous response, the specification, and PCT/US96/02424, does recite support at for example, at page 32, lines 23 to page 33, line 2, which discloses selecting hydrophilic amino acid sequences to generate antibodies. In addition, page 32, lines 14 to 17 of the specification as originally filed (and PCT/US96/02424) recite that "with the protein sequence information, antigenic areas may be

identified and antibodies directed against these areas may be generated and targeted to the prostate cancer for imaging the cancer or therapies." (Emphasis added). Moreover, the specification as originally filed (and PCT/US96/02424) state that the "antigen has the characteristics of a membrane spanning protein with the majority of the protein on the exofacial surface" at page 60, lines 18-21. (Emphasis added). Furthermore, the specification (and PCT/US96/02424) state at page 62, lines 16-18 "[a]ntibodies against PSM antigen coupled with a cytotoxic agent will be useful to eliminate prostate cancer cells". (Emphasis added).

In the February 22, 2008 Office Action, the Examiner asserted, however, that support for the claimed method would "require a specific antibody that has been mapped or tested to specifically bind to the outer membrane of the protein" (emphasis added). Applicants note, however, that the standard for complying with the written description requirement, as set forth in M.P.E.P. §2163, is that "the specification must describe the invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." Thus, the Examiner's statement appears to be introducing a new and additional requirement regarding support. As such, applicants maintain that the Examiner's objection is improper. In addition, in view of the support recited hereinabove which is found in the priority documents, applicants maintain that the invention as claimed is clearly entitled to the currently claimed priority. Accordingly, applicant respectfully requests reconsideration of the priority date being accorded by the Examiner to the presently claimed invention.

**Claims Rejected under 35 U.S.C. §112 (First Paragraph,
Written Description)**

The Examiner rejected claims 21 and 23-25, 27 and 29-31 as failing to comply with the written description requirement as drawn to new matter. The Examiner asserted that the claims as worded would be "understood or interpreted by [one] skilled in the art as the antibody having the affinity to (b[i]nd] to) the cytotoxic agent."

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution and without conceding the correctness of the Examiner's position, applicants have hereinabove amended claim 21, from which the remaining rejected claims depend, to recite "an antibody coupled to a cytotoxic agent". The specification provides support for such a therapy. For example, the specification (and PCT/US96/02424) state at page 62, lines 16-18 "[a]ntibodies against PSM antigen coupled with a cytotoxic agent will be useful to eliminate prostate cancer cells". Accordingly, applicants maintain that the claims as pending are sufficiently described in the specification as filed, and as such raise no issue of new matter.

Claims rejected under 35 U.S.C. §102(b)

Murphy et al. (WO9947554, published 9/23/1999)

The Examiner rejected claims 21, 23, 25, 27 and 29-31 under 35 U.S.C. §102(b) as being anticipated by Murphy et

Applicants: Ron S. Israeli, et al.
Serial No.: 10/751,346
Filed: January 2, 2004
Page 7

al. (WO9947554, published 9/23/1999) "as evidenced by [the] sequence search result."

In response, applicant respectfully traverses the Examiner's rejection. Applicants note that, Murphy et al., was published in September 23, 1999, i.e. after the filing date of PCT/US96/02424 (February 23, 1996). In addition, applicants have noted hereinabove how the claims as amended hereinabove are supported by the priority document PCT/US96/02424. As such, Murphy et al. is not prior art to the claims pending in the subject application. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Horoszewicz et al. (U.S. Patent No. 5,162,504, issued 1992)

The Examiner rejected claims 21, 23-25, 27 and 29-31 under 35 U.S.C. §102(b) as being anticipated by Horoszewicz et al. (U.S. Patent No. 5,162,504, issued 1992) "as evidenced" by Horoszewicz et al. (Anticancer Research, 7:927-935, 1987) and Murphy et al. (WO9947554, published 9/23/1999).

The Examiner asserted, inter alia, that U.S. Patent No. 5,162,504 disclose an "antibody to the PSMA, 9H10-A4, [that] only recognizes the surface of prostate cancer cells, LNCap." However, U.S. Patent No. 5,162,504 nowhere states or indicates that 9H10-A4 is an antibody to PSMA. Moreover, U.S. Patent No. 5,162,504 nowhere states or indicates that 9H10-A4 binds to an outer membrane domain of PSMA, nor that it is conjugated to a cytotoxic agent. The Examiner states that the above statement is "evidenced" by the abstract of Horoszewicz et al.

Applicants: Ron S. Israeli, et al.
Serial No.: 10/751,346
Filed: January 2, 2004
Page 8

(Anticancer Research, 7:927-935, 1987). However, there is no statement in the abstract regarding 9H10-A4 binding to PSMA.

Accordingly, U.S. Patent No. 5,162,504 does not teach all the elements of the method as claimed. As such, the anticipation rejection is improper and should be withdrawn.

Claims rejected under 35 U.S.C. §103(a)

The Examiner rejected claims 21, 23-25 and 30-31 under 35 U.S.C. §103(a) as obvious over Horoszewicz et al. (U.S. Patent No. 5,162,504, issued 1992) in view of Liu et al. (Cancer Research, 57:3629-3634 (1997) as evidenced by a sequence search result and Israeli et al. (Cancer Research, 53:227-230 (1993)).

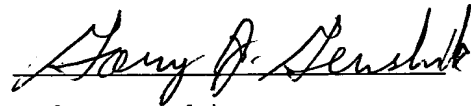
In response, applicants respectfully traverse the Examiner's rejection. Applicants note Liu et al. (1997) relied on by the Examiner to cure the deficiencies of U.S. Patent No. 5,162,504 has a publication date after the claimed priority date, i.e. after the filing date of PCT/US96/02424 (February 23, 1996). In addition, applicants have noted hereinabove how the claims as amended hereinabove are supported by the priority document PCT/US96/02424. As such, Liu et al. is not prior art to the claims pending in the subject application and the obviousness rejection is thus improper and should be withdrawn.

Applicants: Ron S. Israeli, et al.
Serial No.: 10/751,346
Filed: January 2, 2004
Page 9

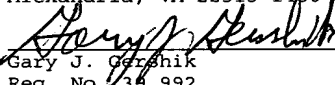
If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed fee of \$525.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
 Gary J. Gershik Reg. No. 39,992	<u>8/22/08</u> Date